

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

BRIGHAM AND WOMEN'S HOSPITAL	:	CIVIL ACTION
INC., et al.	:	
	:	
v.	:	
	:	
TEVA PHARMACEUTICALS USA, INC.,	:	
et al.	:	NO. 08-464

MEMORANDUM

Bartle, C.J.

September 21, 2010

Plaintiffs, Brigham and Women's Hospital, Inc., NPS Pharmaceuticals, Inc., and Amgen Inc. (collectively "plaintiffs") have sued Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries Ltd., and Barr Laboratories, Inc. (collectively "defendants") for infringement of pharmaceutical patents No. 6,211,244 (the "'244 patent"), 6,313,146 (the "'146 patent"), 6,011,068 (the "'068 patent"), and 6,031,003 (the "'003 patent"). Each of these patents states claims relating to the production or medicinal use of cinacalcet hydrochloride compounds that Amgen sells under the trade name Sensipar. Sensipar is used to treat secondary hyperparathyroidism and hypercalcemia, diseases common in patients on dialysis for chronic renal failure.

Before the court are plaintiffs' motion to strike the expert witness report of defendants' patent law expert, Cameron K. Weiffenbach, and plaintiffs' motion to preclude defendants' new and non-particularized inequitable conduct defenses.

Defendants' acknowledge infringement of plaintiffs' patents but allege in their defenses and counterclaims that each patent is unenforceable due to plaintiffs' inequitable conduct before the U.S. Patent and Trademark Office ("PTO") during the prosecution of those patents. Specifically, defendants allege that plaintiffs engaged in inequitable conduct in obtaining each patent in suit by not providing the relevant patent examiner with certain material information. In their counterclaim, defendants aver that plaintiffs improperly failed to make two disclosures to the PTO. First, defendants maintain that plaintiffs failed to disclose the '244 patent application to the examiners simultaneously considering the '146, '068 and '003 patent applications. Second, defendants assert that plaintiffs failed to disclose the application for, and once granted, the existence of patent 5,648,541 (the "'541 patent"), which also contains claims pertaining to cinacalcet hydrochloride compounds.

I.

Plaintiffs first ask the court to "strike" Weiffenbach's report, which defendants served on plaintiffs following the close of fact discovery. Plaintiffs in effect seek to prevent defendants from offering trial testimony from Weiffenbach, who is a lawyer with a master's degree in chemistry. Weiffenbach's report discusses several legal principles, including the doctrine of inequitable conduct, the duties of disclosure and inquiry in patent prosecutions, obviousness-type double patenting, and the effect of the TRIPS Agreement and GATT

Amendment on patent terms. The report also sets forth Mr. Weiffenbach's opinion that the '244 patent application was material to the '068 and '003 patent applications, that the '541 patent should have been disclosed to the examiner considering the '244 patent application, and that the materials Weiffenbach reviewed tend to show plaintiffs acted with an intent to deceive the PTO. Finally, the report describes various PTO practices and procedures.

As a general rule, expert witnesses may not testify as to the law governing a dispute or offer conclusions concerning a party's compliance with legal duties. Berckelely Inv. Group, Ltd. v. Colkitt, 455 F.3d 195, 217 (3d Cir. 2006); United States v. Leo, 941 F.2d 181, 196 (3d Cir. 1991). The law of this district is clear that experts in patent cases may not opine on whether a party engaged in inequitable conduct, discuss whether certain information was material to a pending patent application, or otherwise provide legal conclusions on "substantive issues of patent law." Proctor & Gamble Co. v. TEVA Pharm. USA, Inc., Case No. 04-940, 2006 U.S. Dist. LEXIS 54260, at \*3-\*4 (D. Del. Aug. 4, 2006); see Revlon Consumer Prods. v. L'Oreal, S.A., Case No. 96-192, 1997 U.S. Dist. LEXIS 4117, at \*5-\*10 (D. Del. March 26, 1997) (gathering cases). Similarly, in this district parties are generally not permitted to explain patent prosecution histories through expert testimony. See Transcript of Proceedings at 16:17 - 21:5, Boehringer Ingelheim Int'l GMBH, et

al. v. Barr Labs., Inc., Case. No. 05-854 (D. Del. Feb. 7, 2008). Weiffenbach's report covers all of these forbidden subjects.

However, as noted above, his report also discusses the practices and procedures of the PTO. The law permits experts in patent cases to offer such testimony. Procter & Gamble Co., 2006 U.S. Dist LEXIS 54260, at \*3-\*4; Revlon Consumer Prods., 1997 U.S. Dist. LEXIS, at \*9-\*10.

Accordingly, plaintiffs' motion to strike the expert report of Cameron K. Weiffenbach will be granted except to the extent that it explains the PTO's practices and procedures.

## II.

Plaintiffs also ask the court to prevent defendants from asserting certain "new and non-particularized inequitable conduct contentions" that they contend are set forth for the first time in the Weiffenbach report. Plaintiffs first take the position that the inequitable conduct described in the Weiffenbach report has not been stated with the particularity required under Exergen v. Wal-Mart Stores, Inc., 575 F.3d 1312 (Fed. Cir. 2009).

Plaintiffs' argument that Exergen controls the outcome of this case is unpersuasive. The Exergen case explains the standard for determining whether a party has made sufficiently detailed allegations to plead inequitable conduct properly under Rule 9(b) of the Federal Rules of Civil Procedure. 575 F.3d at 1328. The pleading requirements of Rule 9(b), as elaborated in Exergen, do not apply to expert witness reports, which are not

pleadings under the Federal Rules of Civil Procedure.<sup>1</sup> Fed. R. Civ. P. 7(a). Nonetheless, assuming that Exergen applies to the inequitable conduct contentions in the Weiffenbach report, the contentions with which plaintiffs take issue are stated with sufficient particularity.

Plaintiffs also assert that the Weiffenbach report sets forth contentions concerning plaintiffs' allegedly inequitable conduct that defendants had not previously pleaded or disclosed during discovery.<sup>2</sup> Plaintiffs identify seven contentions that they assert are new or different from defendants' positions in pleadings or interrogatory responses. Having reviewed each of the alleged new contentions and the defendants' pleadings, interrogatory responses, and expert reports, the court will limit defendants to introducing evidence of contentions adequately disclosed in their pleadings or through discovery.

Plaintiffs argue that the Weiffenbach report identifies for the first time that plaintiffs' attorneys Drs. Richard Warburg and Sheldon Herber breached a "duty to inquire" into the relevance of the '541 patent while prosecuting the '244 patent application. While defendants did not previously mention any

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1. Plaintiffs specifically state that their motion does not challenge the sufficiency of defendants' pleadings or interrogatory responses.

2. Plaintiffs have not argued that defendants violated their duty to supplement timely their interrogatory responses under Rule 26(e)(1)(A) of the Federal Rules of Civil Procedure or that the allegedly new inequitable conduct contentions should be stricken pursuant to Rule 37(c)(1).

"duty to inquire," defendants did state in their October 23, 2009 interrogatory response that both Drs. Warburg and Herber may have had knowledge of the '541 patent and may have had a duty to disclose that patent during the '244 prosecution. The court finds that the "duty to inquire" is sufficiently similar to defendants' stated response that plaintiffs were on notice of this contention.

Plaintiffs contend that the Weiffenbach report states for the first time that claim 3 of the '244 patent is patentably indistinct from claim 26 of the '068 patent, when defendants' previous interrogatory answer stated that it was claim 5 of the '244 patent that was indistinct from claim 26 of the '068 patent. Defendants note that all their allegations of claim overlaps will be presented through their expert medicinal chemist, Dr. Weinstock, to whose report plaintiffs have not objected. Plaintiffs could anticipate that in a pharmaceutical patent infringement case the defendants' contentions of claim overlaps would be presented in a medicinal chemist's expert witness report. The court observes, however, that the '244 patent contains 44 claims, the '146 patent contains 55 claims, the '068 patent states 103 claims, and the '003 patent states 145 claims. In light of the large number of claims potentially in issue, defendants will be limited to presenting evidence of anticipated, obvious, or patentably indistinct/overlapping claims specifically disclosed and identified as such in their interrogatory responses or in Dr. Weinstock's expert witness report.

Similarly, plaintiffs argue that the Weiffenbach report is the first time defendants assert that claim 83 of the '003 patent is indistinct from claim 21 of the '244 patent. Previously defendants' interrogatory response had identified claim 85 of the '003 patent as indistinct from claim 26 of the '244 patent. Again, defendants will be allowed to present only evidence concerning anticipated, obvious, or overlapping claims identified in either their interrogatory responses or the Weinstock report.

Plaintiffs contend that the Weiffenbach report alleges for the first time that the '541 patent was material to the '244 patent prosecution because of specific cinacalcet compounds claimed in the '244 application. Plaintiffs maintain that it was the defendants' previous position that the '541 patent was material to the '244 patent prosecution only because of the '541 patent's claimed process for preparing the R enantiomer of the cinacalcet compound. Once again, defendants will be allowed to present only evidence concerning anticipated, obvious, or overlapping claims identified in either their interrogatory responses or the Weinstock report.

Plaintiffs assert that defendants are now poised to argue that a patent examiner who saw the '541 patent while examining the '244 patent application would have rejected that application based on anticipation, whereas previously defendants had said the '541 patent would cause the examiner to reject the '244 application based on obviousness-type double patenting.

Defendants' counterclaim and interrogatory response specifically state that the examiner's rejection would be for obviousness-type double patenting, but plaintiffs do not explain why this shift in the examiner's hypothetical rejection is prejudicial. An anticipation argument requires a comparison of the allegedly anticipated invention to only one prior art reference.

Therasense, Inc. v. Becton, Dickson & Co., 593 F.3d 1325, 1332-33 (Fed. Cir. 2010). Defendants have consistently asserted that the '541 patent claims subject matter that overlaps with the '244 patent. Under either an anticipation or obviousness-type double patenting argument, plaintiffs were aware they would have to rebut comparisons between the claims of the '244 and '541 patents. Thus, the court will not preclude defendants from arguing at trial that the '541 patent's claims anticipated the '244 patent's claims.

Plaintiffs maintain that the Weiffenbach report identifies for the first time attorney Michael Paul as having breached a duty to disclose the '244 patent application during prosecution of the other patents in suit. While other individuals were mentioned earlier, plaintiff is correct that Paul was not previously identified. After the deposition of James Jensen, defendants agreed not to depose Paul if plaintiffs agreed not to call him as a witness. Plaintiffs agreed. Under the circumstances, it would be improper for defendants to assert inequitable conduct on the part of Paul now that plaintiffs have agreed not to call him as a witness at trial.



Plaintiffs complain that the Weiffenbach report is defendants' first mention of a PTO office action issued during the '244 patent prosecution that purportedly demonstrates the materiality of the '244 patent application to the other patents in suit. Specifically, plaintiffs argue that defendants should be barred from asserting that plaintiffs were obligated to disclose claim rejections the PTO made during the '244 patent prosecution based on "the Brown '569 patent." Defendants explain that these claim rejections were disclosed in their interrogatory response by referencing a 76-page series of Bates-stamped documents that includes the PTO office action. Similarly, defendants' counterclaim alleges that plaintiffs breached their duty to disclose by not citing to the examiners of the patents in suit "the arguments made by the examiner or the patentees through office actions or amendments during prosecution of the '244 patent." Accordingly, defendants' allegations concerning the PTO office action were disclosed and will be allowed at trial.

For the reasons set forth above, plaintiffs' motion to preclude defendants' new and non-particularized defenses will be granted in part and denied in part.